

## REMARKS

### Submission Under 37 C.F.R. 1.114 Includes Amendment Filed October 17, 2003

Applicants filed an Amendment Under 37 C.F.R. §1.116 on October 17, 2003. Entry of that Amendment is respectfully requested.

### Status of the Claims

Claims 1-8, 10-27, 29-39, and 87-89 are pending. Claims 1-8, and 10-22 are allowed. Claims 26-27, 29-32, and 34-39 are objected to. Claims 23-25 and 33 stand rejected.

The only issue precluding allowance of all pending claims in this application remains the rejection under 35 U.S.C. § 102, discussed in greater detail, below.

### Issues Under 35 U.S.C. § 102

Claims 23-25, and 33 are rejected under 35 U.S.C. § 102 (b) as allegedly being anticipated by Futaki et al., LaPointe et al., Hamilton et al., Belvisi et al., or Lundy et al. (cited in the Office Action as WO 98/50033). This rejection is respectfully traversed. As stated in the record, Applicants respectfully submit that the cited references are deficient at least in view of the fact that they fail to disclose or suggest the step of detecting a COX-2 specific metabolite, or detecting a metabolite of a COX-2 selective substrate.

In the Amendment under 37 C.F.R. 1.116 filed on October 17, 2003, Applicants incorporated claim 28, which was free from any rejection, into independent claim 23.

In the Advisory Action, the position of the Office is that such action is “unpersuasive” with respect to overcoming the outstanding rejection. Accordingly, the rejection stands. Applicants respectfully submit that such action is clearly improper. The record is clear that previously pending claim 28 was not part of the outstanding rejection. More particularly, previously pending claim 28 was addressed in a previous Office Action (paper no. 14) under the heading “Allowable Subject Matter” and was objected to merely because of its dependence on the rejected base claim (claim 23).

It is well settled that when an allowed (i.e., free from prior art) dependent claim is incorporated into a rejected base claim, the base claim, which then includes the allowed feature(s) of the dependent claim, is free from the prior art rejection. It is procedurally improper to indicate that the incorporation of an allowable claim into a rejected base claim (effectively presenting an allowable dependent claim in independent form) is unpersuasive to overcome an art rejection, and still maintain the finality of that rejection. (Applicants note that previously pending claim 28 is still indicated as “objected to” in the Advisory Action.) In other words, the Office cannot maintain the position that a claim is free from prior art, and at the same time maintain that incorporating that claim into the rejected base claim does not overcome a prior art rejection.

The incorporation of previously pending claim 28 should have been sufficient to obtain allowance of claim 23. Alternatively, it should have invited a new, non-final rejection that addressed the features of claim 23. Furthermore, it cannot be said that a final rejection was necessitated by the amendment, since the claim at issue was presented as an original claim.

Applicants respectfully submit that they were prejudiced by the improper maintenance of the final rejection. While Applicants understand that the Examiner had no control over the location and treatment of the Application during the scanning process (in fact, the Examiner was quite helpful in trying to locate the file during this time), Applicants submitted their response on October 17, 2003. On December 17, 2003, Applicants were forced to file a Notice of Appeal with a full three month extension of time. Following the Notice of Appeal, this RCE was required to toll the response period and remove the finality of the rejection. Significant fees were necessary during this period.

Accordingly, allowance of the claims or at the very least removal of the final rejection is requested. Applicants submit that such action is proper and earnestly solicited.

In the above amendment, Applicants further distinguish the claims from the applied references. In the Belvisi reference discussed in the Advisory Action, post-mortem collection of human airway smooth muscle tissue, which was then finely chopped, was required. As stated in the record, the present invention provides significant advantages over the prior art, such as the ability to detect and/or quantify COX-2 directly in a patient or sample thereof.

Additionally, as stated in the record, the references disclose methods of detecting COX-2 enzymatic activity by detecting 6-keto-PGF<sub>1α</sub>. 6-keto-PGF<sub>1α</sub> is a metabolite of PGH<sub>2</sub>, which is the product of COX oxygenation of arachidonic acid (AA). AA oxygenation of COX-2 has been an important basis of the rejections. However, also as stated in the record, AA is oxidized at equivalent rates by COX-1 and COX-2. This is shown in the specification (e.g., Fig. 9), and is known in the art. See, for example, Attachment A. Fig. 1 and the relevant discussion in the

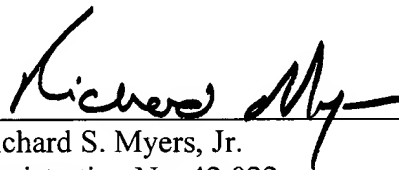
Attachment shows oxygenation rates of AA, and indicates that there is no inherent preference of COX-1 or COX-2.

In view of the above, Applicants respectfully request that this rejection be withdrawn.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicants hereby petition for a two-month extension of time for filing a response. The fee of \$210 is included in the attached RCE filing fee.

If the Examiner has any questions concerning this election or the Application in general, she is respectfully requested to contact the undersigned at the number listed below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Richard S. Myers, Jr.", is written over a horizontal line.

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